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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/341,641	09/09/1999	GUNTER SCHMIDT	020600-280	5378

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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 03/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

112

Office Action Summary

Application No.

09/341,641

Applicant(s)

SCHMIDT ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-25 and 27-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-25 and 27-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the Claims

1. This action is in response to papers filed 7 December 2004 in which a sequence listing in paper and computer-readable format was submitted, the specification was amended, claims 21, 23-24 were amended and claims 26, 33-43 were canceled. All of the amendments have been thoroughly reviewed and entered.

The previous objection to the specification and rejections under 35 U.S.C. 112, first and second paragraph and under 35 U.S.C. 103 in the Office Action dated 7 June 2004 are withdrawn in view of the amendments. The previous rejections under 35 U.S.C. 102(b) and obviousness-type double patenting are maintained. Applicant's arguments have been thoroughly reviewed but are not found persuasive to overcome the prior art rejections.

Response to Arguments

2. Applicant asserts the instant invention differs from the prior art in that the unique amount of each DNA molecule permits sequencing without spatial resolution because a relationship exists between the amount of each DNA and the cleaved mass label such that the sequence of DNA is resolved after sufficient number of ligation cycles (pages 15-17 of the response). The argument is not found sufficient to overcome the rejection because the claims, as written, do not define the inventive relationship between the unique amount of DNA and cleaved mass label. Therefore, the arguments are not persuasive because they are not commensurate in scope with the claims.

However, amendments clearly defining this relationship, as supported by the specification, will be considered. It is suggested that the claims be amended to clearly define the quantitative relationship between the amounts of DNA and cleaved label whereby the sequence of the DNA is resolved by analysis of cleaved label having that relationship.

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Claims 21-25 and 27-32 are under prosecution.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 21-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Southern et al (WO 95/04160, published 9 February 1995).

Regarding Claim 21, Southern teaches a method for sequencing a single stranded DNA molecules, the DNA having a primer to provide a double stranded portion (Fig. 4-5), the method comprising contacting the DNA with hybridization probes comprising a label cleavably attached to a known base sequence of known length, the contacting being in the presence of a ligase to thereby ligate the double stranded portion to a probe complementary to the DNA to form an extended double stranded portion, removing un-ligated probes, cleaving to release the label, recording the quantity of the label, activating the extended portion to enable ligation and repeating the steps of contacting, cleaving and activating to determining the sequence of DNA molecules (page 15, line 20-page 17, line 5). Furthermore, Southern specifically teaches method simultaneously sequences a plurality of different sequences (page 17, lines 1-5). And Southern teaches the method wherein the sequencing is without spatial separation i.e. the tags are cleaved and detected (page 16, lines 5-10).

Because the tags are cleaved, the sequencing is performed without spatial separation of the tags (e.g. Example 18, pages 45-46). The instantly claimed "unique amount" is given its broadest reasonable interpretation consistent with the specification wherein it is not described

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and consistent with the claim wherein the uniqueness of the amount is not defined. As such, the "unique amount" can be interpreted as each DNA molecule has a unique amount (e.g. one spot of vector sequence), but not different from the amount of other DNA molecules.

Given the broadest reasonable interpretation of the claims, Southern teaches the claimed invention.

The courts have stated that claims must be given their broadest reasonable interpretation consistent with the specification *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969); and *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (see MPEP 2111).

Regarding Claim 22, Southern teaches the method wherein an array (plurality) of probes comprising all possible n-mers are contacted with DNA (page 15, lines 28-34).

Regarding Claim 23, Southern teaches the method wherein the target DNA is obtained by sorting the DNA into sub-populations and selected one as a target e.g. DNA clones are hybridized to primers (sorted) and immobilized DNA molecules are sequenced (e.g. page 17, lines 24-31).

Regarding Claim 24, Southern teaches the method wherein the DNA is fragmented to have sticky ends of known length which are sorted onto subpopulations according to their sticky ends (Fig. 5).

Regarding Claim 25, Southern teaches the method wherein each DNA is immobilized at one end i.e. via hybridization to immobilized primer (Fig. 5).

Regarding Claim 26, Southern teaches the method wherein the label comprises a mass label and the quantity of the label is recorded using a mass spectrometer after label release (page 14 and Fig. 1-4).

Regarding Claim 27, Southern teaches the method wherein the known base is blocked at the 3' OH (page 16, lines 10-25 and Fig. 4).

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Regarding Claim 28, Southern teaches the method wherein the cleaving unblocks the 3' OH of the extended double stranded portion (page 16, lines 10-25 and Fig. 4).

Regarding Claim 29, Southern teaches the method wherein the label of each probe is cleavable attached to the 3' OH (page 16, lines 10-25 and Fig. 4).

Regarding Claim 30, Southern teaches the method wherein the probe is unphosphorylated at the 3' and 5' ends and the method comprises phosphorylating the 5' OH of the extended double stranded portion (page 16, lines 10-25 and Fig. 4).

Regarding Claim 31, Southern teaches the method wherein the predetermined length is from 2 to 6 (page 2, lines 1-8 and Claim 4).

Regarding Claim 32, Southern teaches the method wherein the predetermined length is 4 (page 2, lines 1-8 and Claim 4).

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18, 20-24, 27 and 28 of copending Application No. 09/462,408. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to

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methods of sequence analysis and differ on y in the arrangement of the limitations within the claim sets. For example, instant Claim 21 requires ligase and ligation while dependent Claim 13 of the '408 application is drawn to ligation. Hence, the claim sets are drawn to methods which are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

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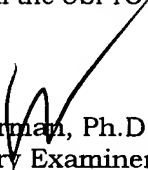
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



BJ Forman, Ph.D.
Primary Examiner
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March 3, 2005